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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,532	12/12/2001	Roberto Villa	9623 V/vmf/as	4029

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EXAMINER
DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N . 10/009,532	Applicant(s) VILLA ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on December 12, 2001 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file and the information referred to therein has been considered, however, Applicant is required to submit a list for consideration by the Office.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 recites the limitation "lipophilic matrix and the optional amphiphilic matrix" in line 10. There is insufficient antecedent basis for this limitation in the claim.

5. Regarding claims 1-14, the phrase "other excipients" renders the claims indefinite because the claims include elements not actually disclosed, thereby rendering the scope of the claims unascertainable.

6. Claim 3 recites the limitation "amphiphilic compounds" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Regarding claim 3, the parenthesis renders the claim indefinite because it is unclear whether the limitations inside the parenthesis are part of the claimed invention.

8. Claim 4 recites the limitation "the lipophilic matrix" in line 2. There is insufficient antecedent basis for this limitation in the claim.

9. Claim 9 recites the limitation "inert /amphiphilic matrix" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 10 recites the limitation "lipophilic/amphiphilic matrix" in 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (EP 0514008).

The claimed invention is directed to oral compositions comprising a lipid matrix, an amphiphilic matrix, a hydrophilic matrix and enteric coating.

Akiyama et al. provides a gastrointestinal mucosa-adherent matrix comprising a viscogenic agent, a matrix containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient and enteric polymers (See p. 2, line 55 to p. 3, line 7). Akiyama et al. includes polymers

containing carboxyl groups, such as acrylic acid polymers, cellulose ethers, such as carboxymethylcellulose, and naturally occurring mucous substances, such as pectin, carrageenan, gums, alginate and waxes, among the viscogenic agents used in the invention (See p. 3, lines 23-56), and teaches that the fatty acids contain 8-40, preferably 12-22 carbon atoms and the lipid, including phospholipids, preferably has a melting point of 40-90°C (See p. 4, line 20 to p. 5, line 6). Akiyama et al. contemplates a great variety of active ingredients, which can be delivered using the system of the invention, including analgesics, hypnotics and sedatives, psychotropic agents, bronchodilators and antitussives (See p. 5, lines 7-17). Akiyama et al. teaches that the composition may comprise an enteric polymer, such as Eudragit, and various additives (See p. 7, line 2 to p. 3, line 13). Akiyama et al. teaches that the matrix may be prepared by dispersing the viscogenic agent, lipid and active ingredient and granules may be manufactured from said matrix (See p. 8, lines 32-53). Finally, Akiyama et al. teaches that the preparations of the invention may be provided in various dosage forms, including pills, tablets and capsules (See p. 10, lines 12-21).

Thus, Akiyama et al. provides controlled release compositions and dosage forms, as claimed in the instant application. Akiyama et al. does not specifically mention that the compositions of the invention are taste-masking, however, it includes the general categories of active ingredients, as claimed in the instant composition. The burden is shifted to Applicant, to show that the compositions disclosed by the prior art would not be capable of masking the unpleasant taste of certain drugs.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Akiyama et al. to device controlled release pharmaceutical compositions for the delivery of drugs in the gastrointestinal tract. The expected result would have been a successful pharmaceutical composition. Because of the teachings of Akiyama et al., that a variety of active ingredients can be delivered by the compositions of the invention, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

13. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (U.S. Patent 6,368,635).

Akiyama et al. provides a gastrointestinal mucosa-adherent matrix comprising a viscogenic agent, a matrix containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient and enteric polymers (See col. 2, lines 35-54). Akiyama et al. includes polymers containing carboxyl groups, such as acrylic acid polymers, cellulose ethers, such as carboxymethylcellulose, and naturally occurring mucous substances, such as pectin, carrageenan, gums, alginate and waxes, among the viscogenic agents used in the invention (See col. 3, line 14 to col. 4, line 8), and teaches that the fatty acids contain 8-40, preferably 12-22 carbon atoms and the lipid, including phospholipids, preferably has a melting point of 40-90°C (See col. 5, lines 37-56).

Akiyama et al. contemplates a great variety of active ingredients, which can be delivered using the system of the invention, including analgesics, hypnotics and sedatives, psychotropic agents, bronchodilators and antitussives (See col. 5, line 57 to col. 6, line 32`). Akiyama et al. teaches that the composition may comprise an enteric polymer, such as Eudragit, and various additives (See col. 9, line 25 to col. 10, line 40). Akiyama et al. teaches that the matrix may be prepared by dispersing the viscogenic agent, lipid and active ingredient and granules may be manufactured from said matrix (See col. 10, line 46 to col. 11, line 45). Finally, Akiyama et al. teaches that the preparations of the invention may be provided in various dosage forms, including pills, tablets and capsules (See col. 13, lines 20-38).

Thus, Akiyama et al. provides controlled release compositions and dosage forms, as claimed in the instant application. Akiyama et al. does not specifically mention that the compositions of the invention are taste-masking, however, it includes the general categories of active ingredients, as claimed in the instant composition. The burden is shifted to Applicant, to show that the compositions disclosed by the prior art would not be capable of masking the unpleasant taste of certain drugs.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Akiyama et al. to device controlled release pharmaceutical compositions for the delivery of drugs in the gastrointestinal tract. The expected result would have been a successful pharmaceutical composition. Because of the teachings of Akiyama et al., that a variety of active ingredients can be delivered by the compositions of the invention, one of ordinary skill in the art would have a reasonable expectation that the

compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

LDNB3

February 10, 2003

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615